K022709 1/2

510(k) Premarket Notification Summary of Safety Information	***Medlite Q-Switched Laser*** ***February 2, 2003***

1. **Device Name:**
   Trade Name: **Medlite Q-Switched Laser**
   Common Names: Surgical Laser
   Classification Name: Instrument, Surgical, Powered, Laser

FEB 2 0 2003

2. **Establishment Name & Registration Number:**
   Name: Hoya-ConBio, Inc.
   Number: Pending

3. **Classification:**
   Title 21, Code of Federal Regulations,

§Sec. 878.4810 Laser surgical instrument for use in general and plastic surgery and in dermatology.

(a) Identification. (1) A carbon dioxide laser for use in general surgery and in dermatology is a laser device intended to cut, destroy or remove tissue by light energy emitted by carbon dioxide. (2) An argon laser for use in dermatology is a laser device intended to destroy or coagulate tissue by light energy emitted by argon. (b) Classification. (1) Class II.

(2) Class I for special laser gas mixtures used as a lasing medium for this class of lasers. The devices subject to this paragraph (b)(2) are exempt from the premarket notification procedures in subpart E of part 807 of this chapter, subject to the limitations in Sec. 878.9.

[53 FR 23872, June 24, 1988, as amended at 61 FR 1123, Jan. 16, 1996; 66 FR 38803, July 25, 2001]

ProCode: 79GEX

4. **Guidance Documents, Performance Standards and Special Controls:**
   At the present time, the following guidance documents are in effect for this device:

Guidance on the Content and Organization of a Premarket Notification for a Medical Laser

Compliance Guide for Laser Products (FDA 86-8260)

Laser Products-Conformance with IEC 60825-1, Am.2 and IEC 60601-2-22; Final Guidance for Industry and FDA (Laser Notice 50)

FDA mandated performance standards for this device exist and are specified under 21 CFR, §1010 and §1040. These standards, including QSR requirements are followed as required by regulation. Voluntary standards such as UL, in-house Standard Operating Procedures and vendor qualification procedures are in place and utilized in the production of the Medlite Q-Switched Laser.

5. **Equivalent Device(s):**
The Medlite Q-Switched Laser claims substantial equivalence to the ***Thermolase SoftLight Laser, K971207*** and the ***Medlite Q-Switched Laser*** previously cleared via ***K983054***. A feature comparison table is included on the following page for visual comparison of equivalence factors.

K022709 2/2

6. Applicant/Sponsor Name / Address:
Hoya-ConBio, Inc.
47733 Fremont Blvd.
Fremont, CA 94538
510.445.4500 - 510.445.4550

7. Company Contact:
Mr. Dan Romitelli
Hoya-ConBio, Inc.
47733 Fremont Blvd.
Fremont, CA 94538
510.445.4500 - 510.445.4550

8. Submission Correspondent:
David W. Schlerf
Buckman Company, Inc.
200 Gregory Lane
Pleasant Hill, CA 94523-3389
925.356.2640 – 925.356.2654 fax
david@fda-help.com

9. Manufacturing Facility:
Hoya-ConBio, Inc.
47733 Fremont Blvd.
Fremont, CA 94538
510.445.4500 - 510.445.4550

10. Description of the Device and Indications for Use:

Feature	**Medlite Q-Switched Laser**	**Medlite Q-Switched Laser, K014234**	**ThermoLase SoftLight Laser, K971207**	SE?
Indications For Use:	The Medlite Q-Switched Laser System is indicated for use in dermatologic and general surgical procedures for ecoagulation and hemostasis. The Medlite Q-Switched Laser System is indicated for use in laser skin resurfacing procedures for the treatment of acne scars and wrinkles.	Identical No	Identical	Yes
Laser Medium:	Nd:YAG	Nd:YAG	Nd:YAG	Yes
Pulse Method:	Q-Switched	Q-Switched	Q-Switched	Yes
Max Power:	30 Watts	30 Watts	30 Watts	Yes
Wavelength:	1064 & 532	1064 &532	1064	Yes
Power Supply:	110/120 VAC - 50/60 Hz 220/240 VAC - 50/60 Hz	110/120 VAC - 50/60 Hz	117/230 VAC - 50/60 Hz	Yes
Pulse Rate:	1, 2, 5, 10, Single Shot	1, 2, 5, 10, Single Shot	1, 2, 5, 10, Single Shot	Yes
Pulse Duration (nsec):	Less than 20	Less than 20	6 - 20	Yes
Beam Delivery:	Handpiece using articulated arm	Handpiece using articulated arm	Handpiece using articulated arm	Yes
Beam Quality:	Multimode	Multimode	Multimode	Yes
Microprocessor Control:	Yes	Yes	Yes	Yes
Manufacturer:	Hoya-ConBio, Inc.	Continuum Electro-Optics, Inc.	ThermoLase Corporation	Yes

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
9200 Corporate Boulevard
Rockville MD 20850

FEB 2 0 2003

Hoya-ConBio, Inc.
c/o Mr. David W. Schlerf
Buckman Company, Inc.
200 Gregory Lane
Pleasant Hill, California 94523-3389

Re: K022709
Trade/Device Name: Medlite Q-Switched Laser
Regulation Number: 21 CFR 878.4810
Regulation Name: Laser surgical instrument for use in general and plastic surgery and in dermatology
Regulatory Class: II
Product Code: GEX
Dated: December 15, 2002
Received: December 31, 2002

Dear Mr. Schlerf:

We have reviewed your Section 510(k) premarket notification of intent to market the device referenced above and have determined the device is substantially equivalent (for the indications for use stated in the enclosure) to legally marketed predicate devices marketed in interstate commerce prior to May 28, 1976, the enactment date of the Medical Device Amendments, or to devices that have been reclassified in accordance with the provisions of the Federal Food, Drug, and Cosmetic Act (Act) that do not require approval of a premarket approval application (PMA). You may, therefore, market the device, subject to the general controls provisions of the Act. The general controls provisions of the Act include requirements for annual registration, listing of devices, good manufacturing practice, labeling, and prohibitions against misbranding and adulteration.

If your device is classified (see above) into either class II (Special Controls) or class III (PMA), it may be subject to such additional controls. Existing major regulations affecting your device can be found in the Code of Federal Regulations, Title 21, Parts 800 to 898. In addition, FDA may publish further announcements concerning your device in the Federal Register.

Please be advised that FDA's issuance of a substantial equivalence determination does not mean that FDA has made a determination that your device complies with other requirements of the Act or any Federal statutes and regulations administered by other Federal agencies. You must comply with all the Act's requirements, including, but not limited to: registration and listing (21 CFR Part 807); labeling (21 CFR Part 801); good manufacturing practice requirements as set forth in the quality systems (QS) regulation (21 CFR Part 820); and if applicable, the electronic product radiation control provisions (Sections 531-542 of the Act); 21 CFR 1000-1050.

This letter will allow you to begin marketing your device as described in your Section 510(k) premarket notification. The FDA finding of substantial equivalence of your device to a legally marketed predicate device results in a classification for your device and thus, permits your device to proceed to the market.

If you desire specific advice for your device on our labeling regulation (21 CFR Part 801), please contact the Office of Compliance at (301) 594-4659. Additionally, for questions on the promotion and advertising of your device, please contact the Office of Compliance at (301) 594-4639. Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21CFR Part 807.97) you may obtain. Other general information on your responsibilities under the Act may be obtained from the Division of Small Manufacturers, International and Consumer Assistance at its toll-free number (800) 638-2041 or (301) 443-6597 or at its Internet address http://www.fda.gov/cdrh/dsma/dsmamain.html

Sincerely yours,

Miriam C. Provost

for Celia M. Witten, Ph.D., M.D.
Director
Division of General, Restorative
and Neurological Devices
Office of Device Evaluation
Center for Devices and
Radiological Health

Enclosure

510(k) NUMBER: K022709

DEVICE NAME : Medlite Q-Switched Laser

INDICATIONS FOR USE:

The Medlite Q-Switched Laser System is indicated for use in dermatologic and general surgical procedures for coagulation and hemostasis.

The Medlite Q-Switched Laser System is indicated for use in laser skin resurfacing procedures for the treatment of acne scars and wrinkles.

PLEASE DO NOT WRITE BELOW THIS LINE - CONTINUE ON ANOTHER PAGE IF NECESSARY

Concurrence of CDRH, Office of Device Evaluation (ODE)

Miriam C. Provost

(Division Sign-Off)
Division of General, Restorative
and Neurological Devices

510(k) Number K022709

Prescription Use ✓ OR **Over-The-Counter Use** _____
(Per 21 CFR 801.109) (Optional format 1-2-96)